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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,473	01/23/2002	Jude S. Sauer	INE-0002C	5120

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EXAMINER

JACKSON, GARY

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/056,473

Applicant(s)

SAUER, JUDE S.

Examiner

Gary Jackson

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) 65-73 and 80-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-64 is/are rejected.
- 7) ☒ Claim(s) 74-79 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION***Double Patenting***

Claims 1-13 and 19-63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,368,334.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter recited in claims 1 and 5 of the present application- an apparatus comprising an elongate body assembly connecting the body portion to the tongue member, and further comprising first and second elongate needles positioned at least partially within the elongate body assembly, said first needle being longitudinally movable by said first lever and said second needle being longitudinally movable by said second lever and a tongue member having a distal section insertable into a wound; and a face opposing the distal section of the tongue member and separated from the distal section of the tongue member by a gap, the face having an area large enough to impede further insertion of the apparatus into the wound. The allowance of this claim would extend the rights to exclude already granted in claims 1-12 of the patent -that right to exclude covering – the apparatus comprising a body portion having an elongate body assembly having a longitudinal axis and extending from the body portion; a tongue member extending from a distal end of the elongate body assembly; a sleeve holder on a distal portion of the tongue member and separated from a proximal portion of the tongue member by a gap; the tongue member having a perimeter at a cross section of the sleeve holder, and at a cross section of the gap, approximately equal to the given circumference of the wound for holding the wound substantially fully open in the gap; a face opposing the sleeve holder across the gap, the tongue member having a cross sectional perimeter at the face larger than the

Art Unit: 3731

circumference of the wound to stop further insertion of the instrument into the wound and a needle slidable from a position in the body assembly, through an opening in the face, across the gap to the sleeve holder.

The transitional phrase "comprising" does not exclude the presence of elements other than an apparatus comprising a body portion having an elongate body assembly having a longitudinal axis and extending from the body portion; a tongue member extending from a distal end of the elongate body assembly; a sleeve holder on a distal portion of the tongue member and separated from a proximal portion of the tongue member by a gap; the tongue member having a perimeter at a cross section of the sleeve holder, and at a cross section of the gap, approximately equal to the given circumference of the wound for holding the wound substantially fully open in the gap; a face opposing the sleeve holder across the gap, the tongue member having a cross sectional perimeter at the face larger than the circumference of the wound to stop further insertion of the instrument into the wound and a needle slidable from a position in the body assembly, through an opening in the face, across the gap to the sleeve holder.

Likewise, if allowed, the claim of the present application, because of the phrase comprising, not only would provide patent protection to the claimed apparatus a body portion having an elongate body assembly having a longitudinal axis and extending from the body portion; a tongue member extending from a distal end of the elongate body assembly.....the tongue member having a cross sectional perimeter at the face larger than the circumference of the wound to stop further insertion of the instrument into the wound and a needle slidable from a position in the body assembly, through an opening in the face, across the gap to the sleeve

Art Unit: 3731

holder already disclosed and covered by the claim in the issued patent. Thus, the controlling fact is that the patent protection for the device, fully disclosed in and covered by the claim of the patent, would be extended by the allowance of the claim in this application.

Furthermore, there is no apparent reason why applicant was prevented from presenting the claim in the present application for examination during the prosecution of the issued patent.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 19, 22, 46, 48-50, 59 and 74-75, are rejected under 35 U.S.C. 102(b) as being anticipated by Klein et al (USP 5,792,152). The patent to Klein et al discloses a tongue member

Art Unit: 3731

at the distal end of the elongate member 10 and a “face” opposing the distal section at ports 20 and 24 and a gap between the said “face” and distal end in figure 2. Concerning claim 4, the members 110 and 114 are levers secured to the body portion. Concerning claim 19, nose piece 14 is considered the tubular portion. Concerning 46, the “window” and “first wall” is the same gap and “face” discussed above respectively. In regards to claims 49-50, the ferrules have not been positively and therefore they have no limiting effect in this instance.

Claims 1-2, 46-50, 59-62 and 74-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Diaz (USP 5,814,065). The Diaz patent discloses an apparatus 10 with a tongue member at the distal end of the elongate member having a face and distal section form at gap 56. Figure 4-7 discloses the method and apparatus of the above claims. The ferrule has not been positively recited and the device is capable of holding a pair of ferrules.

Claims 74-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Sauer et al (USP 5,431,666) (Sauer ‘666). The Sauer ‘666 patent teaches the method of approximating tissue sections by the manipulating steps of claims 74-79. See column 8, lines 26-58 and column 11, line 56- column 12, lines 1-2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3731

Claims 14-18 and 74-75 are rejected under 35 U.S.C. 103(a) as being obvious over Sauer et al (USP 5,556,686) (Sauer '686).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The patent to Sauer '686 discloses a needle and ferrule combination wherein the needle is snugly fitted into the ferrule. Sauer '686 teach that the needle and ferrule maybe frictionally fitted but suggest that the engagement maybe mechanically secured. It would have been obvious to one having ordinary skill in the art to provide the reference device with a groove needle and tongue on the ferrule for a mechanical engagement between the two.

Art Unit: 3731

Claim Rejections- 35 USC § 112

Claims 51-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Concerning claim 51 and related claims, the examiner is not clear on the distinction between the "tip" in claim 46 and "tongue" in claim 51. Please explain.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary Jackson whose telephone number is (703) 308-4302. The examiner can normally be reached on Mon.-Thurs. 7:30 am to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on (703) 308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Jackson
Primary Examiner
Art Unit 3731



gj
September 13, 2004